DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 7, 2016

Tellos Medical AB
Mr. Anders Petersson
CEO
Nedergardsgatan 5
Goteborg, 41654
SWEDEN

Re: K143445
Trade/Device Name: Tellos ISQ Buddy
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EKX
Dated: November 30, 2015
Received: December 2, 2015

Dear Mr. Petersson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143445

Device Name
Tellos ISQ Buddy

Indications for Use *(Describe)*
Tellos ISQ Buddy is indicated for use in measuring the stability of dental implants in the oral cavity and the maxillofacial region.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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1. 510(k) Summary

1.1 Submitter

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Contact person: Anders Petersson
This Summary is made on January 2, 2016

1.2 Device name

Proprietary name:	Tellos ISQ Buddy
Common name:	Dental implant stability analyzer
Accessories name:	ISQ Peg
Regulation Number	872.4200
Classification Product Code	EKX

1.3 Identification of Predicate Device

The predicate device trade name:	Osstell ISQ
Accessories name:	SmartPeg

Predicate Device 510(k) information:

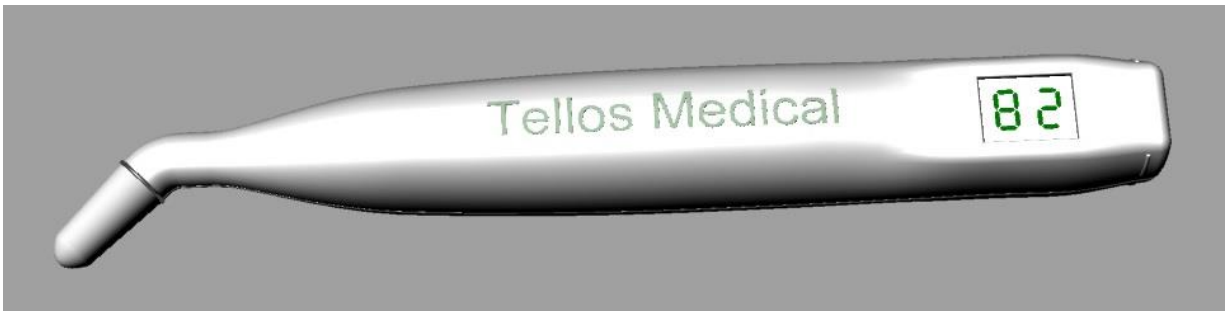
Device Classification Name	Handpiece, Direct Drive, AC-Powered
510(k) Number	K082523
Device Name	OSSTELL ISQ IMPLANT STABILITY METER
Regulation Number	872.4200
Classification Product Code	EKX

1.4 Device description

1.4.1 Description

The Tellos ISQ Buddy measurement system consists of:

Tellos ISQ Buddy Instrument	Hand-held instrument
ISQ Peg Driver	Driver to attach the ISQ peg to the implant
Tellos ISQ Buddy Charger	100-240 VAC to 5VDC charger for the instrument batteries
ISQ Peg	Measurement pin to attach to the implant. Different pins are available to fit different implant types.



Tellos ISQ Buddy Instrument

ISQ Peg Driver

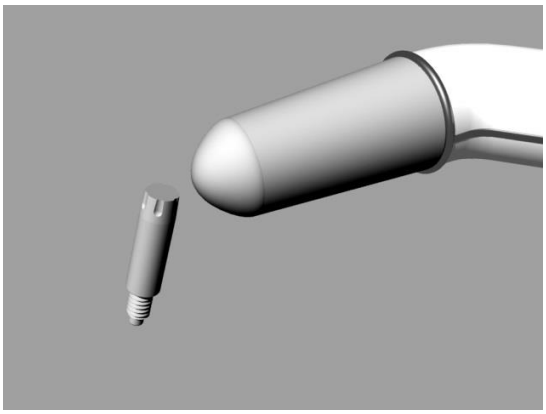
ISQ Peg

Tellos ISQ Buddy Charger

1.4.2 Basic principle and functionality

The Tellos ISQ Buddy instrument is a hand-held, battery-driven device for measuring the relative stability of a dental implant.

A small pin “ISQ peg” is attached to the dental implant by a screw-connection, with the Peg Driver. The pin has a small magnet incorporated into its top. The instrument is held towards the ISQ Peg, and sends short magnetic pulses that bring the pin into vibration. After a pulse has been sent, the instrument measures the vibration by sampling the signal from the alternating magnetic field that follows from the vibrating pin. The frequency of the signal is determined by the instrument and is presented as an “ISQ-value”, 1 to 100, where a higher number means higher stability. The measurement takes about 1 second.



Instrument tip held towards an ISQ Peg

1.4.3 Technical details

The instrument consists of a microcontroller and circuits to send the magnetic pulses, to receive the measurement signal, and to present the measurement value. A circuit for battery-charging is also included. Two 2-digit LED displays, one on each side of the instrument, show the measurement value and also communicate possible error codes and software id number at start-up. One operating key is used to turn the instrument on and off.

The electronics are contained in a plastic body, which is sealed except for the back of the instrument which has a charging connector. The plastic body is made from PC/ABS plastic except for the tip, which is made from PEEK. No part of the instrument is intended to contact the patient; however there can be unintentional contact with the tip of the instrument.

The instrument is battery-driven and contains re-chargeable NiMh-batteries. The batteries can be charged during use, but it should not be attached while measuring due to the risk of power line interference making it impossible to measure. For safety, a charger complying with IEC 60601-1 is used. The charger connector is of a type that does not allow other chargers to be connected, thereby eliminating the risk of the wrong charger being used.

1.4.4 Materials used

Instrument body: PC/ABS
Instrument tip: PEEK (USP VI)
Instrument seal: Silicone (USP VI)
Instrument key: Silicone (USP VI)
ISQ Peg Driver: Stainless steel, ASTM F899
ISQ Peg: Titanium grade 5, ASTM F136

1.5 Indications for Use

Tellos ISQ Buddy is indicated for use in measuring the stability of dental implants in the oral cavity and the maxillofacial region.

1.6 Comparison and differences to the Predicate Device

The instrument functions the same way as the predicate device regarding the measurement principle and technology used. The differences are in the handling; Tellos ISQ Buddy is a hand-held instrument while the predicate device consists of two parts; the instrument and the measurement probe.

Tellos ISQ Buddy has no memory to store the measurement values; the predicate device has a memory that stores the measurements. The predicate device also has an inbuilt clock timer, and a computer connection for transferring measurement values. Tellos ISQ Buddy has no timer or computer connection. The lack of these features (memory, timer, data transfer) is not considered to be an inconvenience for the user. Instead, it decreases the risk of mixing up values with each other.

		510(k) submission	**Predicate Device**
Device name		Tellos ISQ Buddy	Osstell ISQ
Company name		Tellos Medical AB	Osstell AB
Product Code/Class		EKX / Class I	EKX / Class I
Regulation number		872.4200	872.4200
Indications for use		The device is indicated for use in measuring the stability of implants in the oral cavity and the maxillofacial region. The differences in Indications for use are based on clarification of the use of the device with dental implants and the anatomical region appropriate for dental implants. This clarification is within the indications for use of the primary predicate and does not change the intended use of the device.	The device is indicated for use in measuring the stability of implants in the oral cavity and craniofacial region.
Target population		Same as predicate device	Patients with one or more dental implants
Anatomical site		Same as predicate device	Oral cavity or craniofacial region
Usage location		Same as predicate device	Dentists office or hospital
Energy used/delivered		Same as predicate device	No energy is intended to be delivered. A small amount of energy could reach the dental implant from the self-vibrating measurement pin.
Technology		Same as predicate device	A microcontroller sends electric pulses to a coil in the instrument tip. As a consequence, magnetic pulses are emitted that affect the pin connected to the implant. The pin then starts to vibrate with its resonance frequency. Vibration creates an alternating magnetic field which is being picked up by another coil in the instrument tip. The electrical signal from the receiving coil is analyzed and the frequency is determined. The Frequency is presented on the display as an "ISQ-value"
Measurement output		Same as predicate device	Osstell ISQ presents the resonance frequency of the ISQ peg as an ISQ number, 1-100. The ISQ number is

			calculated from the resonance frequency.
Operation		The operating key is pushed and the instrument is held towards the attached ISQ peg. The instrument then presents the ISQ value.	Any key is pushed and the measurement probe is held towards the attached SmartPeg. The instrument then presents the ISQ value.
System components		Tellos ISQ Buddy instrument, ISQ Peg, ISQ Peg Driver and instrument charger.	Osstell ISQ instrument, measurement probe, SmartPeg and instrument charger.
Power, weight & size		3VA, 0.1 Kg, 200 x 30 mm	8 VA, 0.4 Kg, 195 x 20 x 45 mm
Materials used		Instrument; PC/ABS and PEEK. Gasket and operating key: Silicone ISQ Peg Driver: Stainless steel ISQ Peg: Titanium	Instrument: Not available Measurement probe: Not available SmartPeg driver: Not Available SmartPeg: Aluminum
Instrument memory		Tellos ISQ Buddy has no data memory. The instrument displays the measurement value after the measurement. The memory is not a necessary feature and the absence of a memory decreases the risk of mixing up values between different implants during a patient session.	Osstell ISQ has a memory for storing measurement values.
Instrument setup-menu		No setup-menu is needed for Tellos ISQ Buddy. The instrument has one operating key and no parameters to change.	Instrument has a setup-menu for various instrument parameters such as display contrast and computer connection.
Data transfer		Since Tellos ISQ Buddy has no memory, there are no data to transfer. This is not a necessary feature, and the absence of a data transfer function decreases the risk of mixing up values between different implants during a patient session.	Osstell ISQ has a cable attachment to a PC computer, for transferring data.
Clock Timer		Since Tellos ISQ Buddy has no memory, there is no need for a clock timer.	Osstell ISQ has a built-in clock timer.
Number of operating keys		Tellos ISQ Buddy has one operating key, used for turning on and off the instrument. Since the instrument has no memory or setup-menu, not more than one key is needed. With one key, the instrument is more intuitive and easier to use, which leaves less room for user errors compared to the predicate device.	Osstell ISQ has 5 operating keys, for working the setup-menu and for navigating the instrument memory.
Display		Tellos ISQ Buddy has two LED-displays; one on each side of the instrument for easy reading.	Osstell ISQ has one LCD display on the instrument.
Measurement pins		Tellos ISQ Buddy uses the Osstell SmartPegs, or corresponding Tellos pins, “ISQ Pegs” from titanium.	Osstell ISQ uses disposable aluminum pins, “SmartPegs”.
Electrical safety		Same as predicate device	Osstell ISQ is designed to the standard IEC 60601-1 Medical Electrical Equipment

1.7 Performance testing

The Tellos ISQ Buddy instrument brings a pin attached to a dental implant into vibration and then measures the resonance frequency of the vibrating pin. The resonance frequency is then presented as an "ISQ-value" 1-100. The predicate device does the same, with the same technological principle. The technical differences concerning the measurements are the electronics and the software since other circuits are used. To make sure the instrument present the same values as the predicate device, a comparison was made with an artificial frequency signal which was varied from 1,000 to 10,200 Hz with a resolution of 100 Hz. The accepted deviation was +/-1 ISQ throughout the scale 1-100 ISQ.

A comparison was also made by measuring on an Osstell SmartPeg attached to an implant embedded in artificial bone. The stability of the implant could be altered by compressing the bone with a varying force. The stability was here varied from 3 to 85 ISQ and the acceptance criteria were +/- 1 ISQ.

Both tests produced ISQ values that were exactly the same (deviation 0 ISQ) for both instruments.

The Tellos Buddy instrument has been tested according to, and found to comply with the following:

- EMC standard IEC 60601-1-2
- Software validation according to FDA guidance for Software Contained in a Medical Device
- Sterilization validation according to ISO 17665-1 and ISO 17665-2
- Biocompatibility standard ISO 10993-1

1.8 Test conclusions

The conclusion from the tests is that Tellos ISQ Buddy produces the same output data as the predicate device in the same measurement situation.

1.9 Substantial Equivalence Conclusion

The purpose of using the instrument is to measure the ISQ-value (the relative stability) of the implant. Tellos ISQ Buddy has the same indications for use, measurement output and technology as the predicate device. The differences in the memory, clock, display and materials used do not change the intended use nor do they affect the safety and effectiveness as compared to the predicate device cleared in K082523.

The device description, software validation, performance testing, sterilization validation and biocompatibility assessment demonstrate the substantial equivalence of the submission device to the identified predicate device.

Therefore, the Tellos ISQ Buddy can be found substantially equivalent to the Osstell ISQ cleared in K082523.